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TRANSMITTAL FORM (to be used for all correspondence after initial filing)		
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	First Named Inventor	Teddy Kosoglou et al.
	Art Unit	1617
	Examiner Name	Shobha Kantamneni
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ENCLOSURES (Check all that apply)

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
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  - ☐ Affidavits/declaration(s)
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Remarks

Request for Reconsideration (6pp)

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

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**RESPONSE UNDER 37 C.F.R. § 1.116
EXPEDITED PROCEDURE EXAMINER
GROUP ART UNIT 1617**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Teddy Kosoglou et al.	Examiner: Shobha Kantamneni
Serial No.: 10/057,339	Group Art Unit: 1617
Filed: January 25, 2002	Atty. Docket No.: CV01490K
For: Combinations of Sterol Absorption Inhibitor(s) with Cardiovascular Agent(s) for the Treatment of Vascular Conditions	Date: March 2, 2005

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Commissioner for Patents
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REQUEST FOR RECONSIDERATION

This is in response to the final Office Action mailed on January 27, 2005 in the above-identified patent application.

Claims 1-3, 22, 23, 33, 34, 43-46 and 49 are pending in this application. Claim 11 was canceled in the previously submitted amendment. Claims 4-10, 12-21, 24-32, 35-42, 47 and 48 have been withdrawn by the Examiner as being drawn to a non-elected invention.

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3/2/2005
Date

At pages 2-3 of the Office Action, claims 1-3, 22-23, 33-34 and 49 have been rejected under 35 U.S.C. §103(a) as obvious over US 5,846,966 ("Rosenblum et al.") in view of Chobanian et al. For brevity, the reasons for rejection are not repeated herein but reference is made to the outstanding Office Action.

Applicants respectfully traverse this rejection and request that the rejection be reconsidered and withdrawn.

When making a rejection under 35 U.S.C. § 103, the Examiner has the burden of establishing a prima facie case of obviousness. In re Fritch, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992). The Examiner can satisfy this burden only by showing an objective teaching in the prior art, or knowledge generally available to one of ordinary skill in the art, which would lead an individual to combine the relevant teachings of the references [and/or the knowledge] in the manner suggested by the Examiner. Id.; In re Fine, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988).

The mere fact that the prior art could be modified does not make the modification obvious unless the prior art suggests the desirability of the modification. In re Fritch, 23 U.S.P.Q.2d at 1784; In re Laskowski, 10 U.S.P.Q.2d 1397, 1398 (Fed. Cir. 1989); In re Gordon, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984).

"It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious....'[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.'" In re Fritch, 23 U.S.P.Q.2d at 1784 (quoting In re Fine, 5 U.S.P.Q.2d at 1600).

"The ultimate determination of patentability must be based on consideration of the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence." Manual of Patent Examining Procedure, (Rev. 1, Feb. 2003) § 716.01(d) and In re Oetiker, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992).

Claims 1 and 49 are drawn to a composition or therapeutic combination comprising a compound of formula (I) (such as ezetimibe) with a cardiovascular agent selected from the group consisting of channel blockers, adrenergic blockers,

adrenergic stimulants, angiotensin-converting enzyme (ACE) inhibitors, antihypertensive agents, angiotensin II receptor antagonists, anti-anginal agents, coronary vasodilators, diuretics and combinations thereof.

Rosenblum et al. disclose a combination of hydroxy-substituted azetidinones (such as ezetimibe) with a cholesterol biosynthesis inhibitor (such as an HMG-CoA reductase inhibitor) for reducing cholesterol and treating atherosclerosis.

Rosenblum et al. do not suggest or disclose a combination of a compound of formula (I) (such as ezetimibe) with a cardiovascular agent *selected from the group consisting of channel blockers, adrenergic blockers, adrenergic stimulants, angiotensin-converting enzyme (ACE) inhibitors, antihypertensive agents, angiotensin II receptor antagonists, anti-anginal agents, coronary vasodilators, diuretics and combinations thereof.*

Chobanian et al. discloses that the antihypertensive agent captopril can be useful for treating atherosclerosis. Chobanian et al. therefore teaches away from the concept of use of two separate compounds (a compound of formula (I) and a separate cardiovascular agent *selected from the group consisting of channel blockers, adrenergic blockers, adrenergic stimulants, angiotensin-converting enzyme (ACE) inhibitors, antihypertensive agents, angiotensin II receptor antagonists, anti-anginal agents, coronary vasodilators, diuretics and combinations thereof* as claimed) because captopril would serve both functions as an antihypertensive and treatment for atherosclerosis.

Therefore, one skilled in the art would not be motivated by the teachings of Rosenblum et al. and Chobanian et al., as combined in the Office Action, to provide a compound of formula (I) and a separate cardiovascular agent *selected from the group consisting of channel blockers, adrenergic blockers, adrenergic stimulants, angiotensin-converting enzyme (ACE) inhibitors, antihypertensive agents, angiotensin II receptor antagonists, anti-anginal agents, coronary vasodilators, diuretics and combinations thereof* as presently claimed.

Applicants respectfully assert that the rejection is based upon improper hindsight reconstruction and respectfully requests that the rejection of claims 1-3, 22-23, 33-34 and 49 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

At page 3 of the Office Action, claims 43-46 have been rejected under 35 U.S.C. §103(a) as obvious over US 5,846,966 ("Rosenblum et al.") and Chobanian et al., further in view of Lelek et al., Myasnikov and Schaarmann et al. For brevity, the reasons for rejection are not repeated herein but reference is made to the outstanding Office Action.

Applicants respectfully traverse this rejection and request that the rejection be reconsidered and withdrawn.

Claims 43-46 depend from claim 1 (drawn to a composition or therapeutic combination comprising a compound of formula (I) (such as ezetimibe) with a cardiovascular agent selected from the group consisting of channel blockers, adrenergic blockers, adrenergic stimulants, angiotensin-converting enzyme (ACE) inhibitors, antihypertensive agents, angiotensin II receptor antagonists, anti-anginal agents, coronary vasodilators, diuretics and combinations thereof).

Claim 43 recites the composition of claim 1, further comprising at least one Omega 3 fatty acid.

Claim 44 recites the composition of claim 1, further comprising at least one natural water soluble fiber.

Claim 45 recites the composition of claim 1, further comprising at least one antioxidant or vitamin.

As discussed above, one skilled in the art would not be motivated by the teachings of Rosenblum et al. and Chobanian et al., as combined in the Office Action, to provide a compound of formula (I) and a separate cardiovascular agent *selected from the group consisting of channel blockers, adrenergic blockers, adrenergic stimulants, angiotensin-converting enzyme (ACE) inhibitors, antihypertensive agents, angiotensin II receptor antagonists, anti-anginal agents, coronary vasodilators, diuretics and combinations thereof* as presently claimed.

Chobanian et al. teaches away from the concept of use of two separate compounds (a compound of formula (I) and a separate cardiovascular agent *selected from the group consisting of channel blockers, adrenergic blockers, adrenergic stimulants, angiotensin-converting enzyme (ACE) inhibitors, antihypertensive agents, angiotensin II receptor antagonists, anti-anginal agents, coronary vasodilators, diuretics and combinations thereof* as claimed) because

captopril would serve both functions as an antihypertensive and treatment for atherosclerosis.

It is asserted in the rejection that Lelek et al., Myasnikov and Schaarmann et al. teach that omega 3 fatty acids, vitamin C and soluble fibers, respectively, are useful for reducing cholesterol and treating atherosclerosis, rendering the combination of these compounds with the above combination obvious.

Following this reasoning, one skilled in the art would combine *every* compound that may have some minor activity in treating some aspect of hypocholesterolemia, which can encompass thousands of compounds. Yet no guidance is provided as to the selection of particular combinations of classes of compounds, i.e., cholesterol absorption inhibitor with *channel blockers, adrenergic blockers, adrenergic stimulants, angiotensin-converting enzyme (ACE) inhibitors, antihypertensive agents, angiotensin II receptor antagonists, anti-anginal agents, coronary vasodilators or diuretics,* or motivation for doing so. Applicants have selected particular classes of compounds, i.e., *channel blockers, adrenergic blockers, adrenergic stimulants, angiotensin-converting enzyme (ACE) inhibitors, antihypertensive agents, angiotensin II receptor antagonists, anti-anginal agents, coronary vasodilators or diuretics* to combine with sterol absorption inhibitor(s) not because a few species of these compounds may have some minor anti-cholesterol effect but because these compounds can have a complementary effect to treatment with the sterol absorption inhibitor.

Applicants respectfully assert that the rejection of claims 43-45 is based upon improper hindsight reconstruction.

Claim 46 recites a pharmaceutical composition for the treatment or prevention of vascular conditions, obesity, diabetes or lowering a concentration of a sterol in plasma of a mammal, comprising a therapeutically effective amount of the composition of claim 1 and a pharmaceutically acceptable carrier.

As discussed above, one skilled in the art would not be motivated by the teachings of Rosenblum et al. and Chobanian et al., as combined in the Office Action, to provide a pharmaceutical composition comprising a compound of formula (I) and a separate cardiovascular agent *selected from the group consisting of channel blockers, adrenergic blockers, adrenergic stimulants, angiotensin-converting*

enzyme (ACE) inhibitors, antihypertensive agents, angiotensin II receptor antagonists, anti-anginal agents, coronary vasodilators, diuretics and combinations thereof as presently claimed.

Applicants respectfully assert that the rejection is based upon improper hindsight reconstruction and respectfully requests that the rejection of claims 43-46 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

Applicants respectfully request that the Examiner return an initialed PTO-1449 form for the Information Disclosure Statement submitted herewith, indicating that the Examiner has considered each of the references cited in the Information Disclosure Statements filed on August 26, 2003 (electronically filed as EFS # 17381, 17382 and 17383), August 23, 2003 (electronically filed as EFS # 17330), and August 21, 2003 (electronically filed as EFS # 17236 and 17267).

In view of the foregoing remarks, it is respectfully submitted that all of the pending claims in the present application are distinguishable from the cited prior art.

Accordingly, reconsideration and withdrawal of the rejection and an early Notice of Allowance are respectfully requested.

Respectfully submitted,

Date: March 2, 2005

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